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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,603	05/04/2006	Jonathan Duffield	8024-012-US	6964

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EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	PAPER NUMBER
1654	
MAIL DATE	DELIVERY MODE
11/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,603	DUFFIELD ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *5-20 and 23-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20061026*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's election of the invention of Group I, claims 1-4, 21, and 22, in the reply filed on September 8, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 5-20 and 23-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 8, 2009.

2. The Sequence Listing filed May 4, 2006 is approved.

3. The abstract of the disclosure is objected to because of the presence of legal phraseology "said". In addition, the Abstract should provide more detail as to the pharmacokinetic properties which are improved by the invention. Correction is required. See MPEP § 608.01(b).

4. Claims 1-4, 21, and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Formula I recited in claim 1 is unclear. The variables R_4 and R_5 are defined by stating that "when" they are substituted with NH_2 and CO_2H, they are any natural amino acid or amino acid surrogate. This use of "when" makes it appear that R_4 and R_5 can have some other definition when they are not substituted with NH_2 and CO_2H, and this other definition is not specified in the claim. Alternatively, it is possible that the reference in the claim to "when substituted with NH_2 and CO_2H" has something to do with the NH and C(=O) groups on either side of R_4 and $(R_5)_n$ in Formula I. However, it is noted that the NH and C(=O) groups of the formula are not identical to the NH_2 and CO_2H groups recited in the quoted claim limitation. Further, when n is an integer greater than 1, the formula does not provide NH and

C(=O) groups for each R_5. It is unclear if NH-R_4-C(=O) and NH-R_5-C(=O) of Formula I constitute amino acid residues, or if R_4 and R_5 by themselves are amino acid residues to which the formula requires the attachment of an additional NH group at their N-termini and of an additional C(=O) group at their C-termini. At claim 1, lines 6-7, the phrase "including mono-, di-, tri-, and tetrasaccharides and larger" is unclear, because it appears to exemplify every possible carbohydrate and is therefore redundant to the phrase "is any carbohydrate". Alternatively, assuming that there are carbohydrates that are not mono-, di-, tri-, or tetrasaccharides or larger, it is not clear if the claim should be interpreted as encompassing all carbohydrates, or if the claim should be limited to those exemplified in the "including…" phrase. At claim 1, lines 8-10, the phrase "any hydroxyl, amino or carboxyl functions are suitably modified by sulfation, alkylation, acylation, deoxygenation, diazotization, pegylation, and silylation" is unclear, because the word "are" in the quoted phrase implies that any hydroxyl, amino and carboxyl functions must be modified, and that unmodified hydroxyl, amino and carboxyl functions are not permitted. Further, the word "and" in the quoted phrase implies that all the listed modifications, i.e. sulfation, alkylation, acylation, deoxygenation, diazotization, pegylation, and silylation, must be present simultaneously. If these interpretations of the claim language are incorrect, clarification of the claim language is necessary. Because of the use of the word "and" at claim 3, line 4, it appears that the claimed compounds are required to possess all of the characteristics simultaneously rather than in the alternative. It is not clear that this is what was intended by Applicant. The phrase "particular sugar motif" and "specific amino acid residue" in claim 4 are indefinite, because the claim does not recite what constitutes the possible

particular sugar motifs and the specific amino acid residues, and it is not possible to guess which sugar motifs and amino acid residues are contemplated by Applicants.

5. Instant claims 1-4, 21, and 22 are not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/598,215 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, does not disclose modification of hydroxyl, amino or carboxyl functions by pegylation; and does not disclose values of n as high as 200.

Instant claims 1-4, 21, and 22 are not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/557,631 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, does not disclose modification of hydroxyl, amino or carboxyl functions by pegylation; does not disclose values of m equal to 2 or 3; and does not disclose values of n as high as 200.

Instant claims 1-4, 21, and 22 are not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/516,838 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, does not disclose modification of hydroxyl, amino or carboxyl functions by pegylation; does not disclose values of m equal to 2 or 3; and does not disclose values of n as high as 200.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-4, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by the Powell et al article (Pharm. Res., Vol. 10, pages 1268-1273). The Powell et al article teaches a peptide comprised of 17 amino acids which is glycosylated at its N-terminal Asn residue. Peptides are synthesized by solid phase synthesis, i.e. the carboxylic acid group of the glycosylated Asn residue will be reacted with the α-amino group of the remainder of the peptide, i.e. SQAVHAAHAEINEAGR. See page 1268, column 2, last paragraph, and page 1271, Figure 3, last peptide. This peptide of the Powell et al article corresponds to Applicants' Formula I in which m=1; R_1 is Glc-NAc; R_2 is NH; R_3 is NH_2-CH-CH_2-C(=O), i.e. an amino acid residue (from that portion of the Asn residue which does not correspond to the R_2 or to the left-most C(=O) group in Applicants' Formula I); and NH-R_4-C(=O)-NH-$(R_5)_n$-CO_2H is SQAVHAAHAEINEAGR. In view of the similarity in structure between the peptide of the Powell et al article and Applicant's claimed compounds, inherently the peptide of the Powell et al article will have increased stability in the presence of peptidases and proteases, increased thermal stability, increased dimer half-life, increased bioavailability, and increased plasma half-life in comparison to a non-glycosylated analog, and inherently the carbohydrate will serve as a stable surrogate for a specific amino acid residue to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the peptide of the Powell et al article and Applicants' claimed compounds to shift the burden to Applicants to provide evidence that their claimed compounds are unobviously different than the peptide of the Powell et al article. Note that a difference in intent or descriptive terminology does not impart novelty or nonobviousness

to product claims where the claimed product is otherwise taught by the prior art.

8. Claims 1-4, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Danishefsky et al (U.S. Patent Application Publication 2004/0102607). Danishefsky et al teach a pentapeptide at its N-terminal Ser residue. Peptides are synthesized by reacting with glycosylated serine with the remainder of the peptide. See, e.g., Figure 2; paragraphs [0138] - [0139]; and page 20, Examples 9-11. This peptide of Danishefsky et al corresponds to Applicants' Formula I in which m=1; R_1 is the N-terminal trisaccharide group; R_2 is O; R_3 is Ac-NH-CH-CH_2, i.e. a combination of alkylacylamino and alkyl groups; and NH-R_4-C(=O)-NH-$(R_5)_n$-CO_2H is the four C-terminal amino acid residues of Danishefsky et al's peptide. In view of the similarity in structure between the peptide of Danishefsky et al and Applicant's claimed compounds, inherently the peptide of Danishefsky et al will have increased stability in the presence of peptidases and proteases, increased thermal stability, increased dimer half-life, increased bioavailability, and increased plasma half-life in comparison to a non-glycosylated analog, and inherently the carbohydrate will serve as a stable surrogate for a specific amino acid residue to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the peptide of Danishefsky et al and Applicants' claimed compounds to shift the burden to Applicants to provide evidence that their claimed compounds are unobviously different than the peptide of Danishefsky et al. Note that a difference in intent or descriptive terminology does not impart novelty or nonobviousness to product claims where the claimed product is otherwise taught by the prior art.

9. Claims 1-4, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Wagstaff et al (U.S. Patent No. 6,525,021). Wagstaff et al teach a hexapeptide corresponding to

the generic contulakin-G formula in which the first ten amino acids are deleted, and in which the N-terminal lysine residue has the structure set forth in Figure 1. As shown in Figure 1, a carbohydrate is attached to the N-terminus of the lysine residue via a linker. Synthesis is by Merrifield solid phase synthesis, i.e. starting with the C-terminal amino acid residue and adding residues in the N-terminal direction. See, e.g., Figure 1; column 3, lines 53-65; column 4, lines 21-22; column 12, line 57 - column 14, line 40; and claim 1, parts (b) and (g), as shown in the Certificate of Correction. This peptide of Wagstaff et al corresponds to Applicants' Formula I in which m=1; R_1 is the carbohydrate group; R_2 is NH; R_3 is C(=O)-CH_2-CH_2, i.e. a combination of acyl and alkyl groups; and NH-R_4-C(=O)-NH-$(R_5)_n$-CO_2H is the Xaa_7-Xaa_8-Xaa_9-Xaa_{10}-Ile-Leu residues of Wagstaff et al's truncated generic contulakin-G formula. In view of the similarity in structure between the peptide of Wagstaff et al and Applicant's claimed compounds, inherently the peptide of Wagstaff et al will have increased stability in the presence of peptidases and proteases, increased thermal stability, increased dimer half-life, increased bioavailability, and increased plasma half-life in comparison to a non-glycosylated analog, and inherently the carbohydrate will serve as a stable surrogate for a specific amino acid residue to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the peptide of Wagstaff et al and Applicants' claimed compounds to shift the burden to Applicants to provide evidence that their claimed compounds are unobviously different than the peptide of Wagstaff et al. Note that a difference in intent or descriptive terminology does not impart novelty or nonobviousness to product claims where the claimed product is otherwise taught by the prior art.

10. Danishefsky et al (U.S. Patent Application Publication 2003/0153492) has been carefully

considered, but is not applied against the instant claims. Danishefsky et al teach peptides which are glycosylated at their N-terminus. However, Applicants' Formula I requires a free carboxylic acid group at the C-terminus of the peptide, which group is not present in compound 53 (see Figure 15) of Danishefsky et al.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/
Primary Examiner, Art Unit 1654

JRussel
November 18, 2009